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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/807,573	06/04/2001	Gerard Alaux	SYL 501	9108

7590 12/22/2003

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EXAMINER	
OH, SIMON J	

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 12/22/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/807,573	ALAUX ET AL.	
	Examiner	Art Unit	
	Simon J. Oh	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 November 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2-4,6-9,11,12 and 14-43* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *4,14,16,17,19,20,22,23,25,26 and 36-43* is/are allowed.

6)☒ Claim(s) *2,3,6-9,11,12,15,18,21,24 and 27-35* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Papers Received

Receipt is acknowledged of the applicant's request for continued examination, amendment, response, and petition for extension of time, all received on 03 November 2003.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 2-4, 6-9, 11, 12, and 14-43 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combined disclosure of Penners *et al.* and Maggi *et al.*

Note that all references to Maggi *et al.* will be made to its English-language equivalent, U.S. Patent No. 6,149,940.

The Penners *et al.* patent teaches a pharmaceutical dosage form designed to have an extended gastric residence time in order to increase the amount of an active substance absorbed in the upper gastrointestinal tract (See Abstract; and Column 1, Lines 1-13 and 35-67). The dosage form comprises the active substance and customary pharmaceutical excipients, as well as a mixture of polymers containing lactam groups and polymers containing carboxyl groups. The dosage form may also optionally comprise a gas-generating component (See Column 3, Line 55 to Column 4, Line 3). Polyvinylpyrrolidone is given as an example of a polymer containing a lactam group. Carboxymethylcellulose and acrylic resins such as those sold under the trade name EUDRAGIT® are given as examples of polymers containing carboxyl groups (See

Column 4, Lines 4-31). The gas-generating component comprises agents that form non-toxic gases when introduced to water or gastric fluid. Such agents include sodium hydrogen carbonate, which may be employed alone or in combination with as acid, such as citric acid (See Column 5, Lines 11-21). The dosage form is preferably in an embodiment in which the active substance is kept in a separate layer from the mixture of polymers containing lactam groups and polymers containing carboxyl groups, such as in a dual-layer tablet (See Column 5, Lines 39-55; and Figures 2-4). Captopril is listed among those active substances that are particularly suitable for the disclosed dosage form (See Column 5, Lines 3-9).

The Penners *et al.* patent does not teach a gastric-retentive dosage form that further comprises a hydrophilic excipient capable of promoting polymer hydration, nor does it disclose lipid substances to be used in the dosage form. The patent does not specifically state that benzamides, alpha-1 antagonists, or those active substances listed in Claim 27 can be used as the active ingredient in the disclosed dosage form.

The Maggi *et al.* document discloses a dosage form for the controlled release of alfuzosin hydrochloride. The dosage form comprises of a layer that swells upon contact with aqueous biological fluids, as well as a layer comprising the active ingredient in a hydrophilic polymer matrix. The dosage form is designed to release the drug at the proximal segments of the gastro-intestinal tract, namely the duodenum and the jejunum (See Abstract; and Column 1, Lines 8-23). The hydrophilic polymers that are primarily used in the tablet include cellulosic polymers as well as acrylic and methacrylic polymers (See Column 2, Line 60 to Column 3, Line 10). In addition, polymeric hydrophilic excipients may be used, including hydroxypropylcellulose, hydroxypropylmethylcellulose, and polyvinylpyrrolidone (See Column 3, Lines 11-30). The

dosage may comprise additional excipients, including hydrophilic excipients such as mannitol, lactose, sorbitol, and microcrystalline cellulose; and hydrophobic excipients such as palmitates, hydrogenated castor oil, and waxes (See Column 3, Lines 43-57). See Examples.

It would be obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Penners *et al.* and Maggi *et al.* into the objects of the instant application. Based on their similar fields of endeavor, one of ordinary skill would be motivated to combine the teachings of Penners *et al.* and Maggi *et al.*, because as stated in *In re Kerkhoven*, 205 USPQ 1069, 1072 (CCPA- 1980), "It is prima facie obvious to combine two compositions, each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition which is to be used for the very same purpose." As this court explained in Crockett, 126 USPQ 186, 188 (CCPA- 1960), the idea of combining them flows logically from their having been individually taught in the prior art. Furthermore, one of ordinary skill would be motivated to combine the disclosures of the prior art in order to incorporate the use of hydrophobic and hydrophilic diluents, as taught in Maggi *et al.*, into the disclosure of Penners *et al.* to provide a means for one of ordinary skill in the art to have greater control in formulating an extended-release dosage form residing in the upper gastrointestinal tract.

Regarding Claims 9, 28, 32, 36, and 40, it is the position of the examiner that the particular drug to be used in the instantly claimed dosage form is not critical to the function of the instantly claimed invention to provide extended release in the upper gastrointestinal tract. It is clear from the disclosure of the instant claims that the function is derived from the materials used in the dosage form, as well as its particular structure. The examiner shifts the burden onto

the applicant to demonstrate the criticality of the presence of a benzamide active ingredient to the function of the invention.

Thus, the claimed invention as a whole is *prima facie* obvious.

Response to Arguments

Applicant's arguments filed 03 November 2003 have been fully considered but they are not persuasive.

Applicant's arguments against the applicant of the principles of *In re Kerkhoven* are rendered moot, as the examiner has relied upon only Penners *et al.* and Maggi *et al.* in the present rejection. See MPEP § 2144.06.

The applicant alleges that Maggi *et al.* is not a suitable reference to be applied because of the "lengthy list of polymers and families of polymers from which one might choose". In view of the broad categories of polymers presented in independent claims 2 and 4, it is the position of the examiner that those polymers and categories of polymers disclosed in Maggi *et al.* are not any broader than those in the instant independent claims. Furthermore, at no point has the examiner ever alleged that the selection of a particular combination of polymers from the prior art would be "obvious to try". The prior art is relied upon for all it contains and fairly teaches. See MPEP § 2111 and 2123.

In view of the teachings of the prior art, the instant claim limitations concerning the selection of one particular polymer or a group of polymers from the same family are not given significant patentable weight. In order to present a stronger case for patentability, the applicant

is invited to present data or evidence showing unexpected results above what has been taught by the prior art.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Simon J. Oh whose telephone number is (703) 305-3265. The examiner can normally be reached on M-F 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

Simon J. Oh
Examiner
Art Unit 1615

sjo

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600